REMARKS

For the reasons discussed below, the rejections are traversed and it is applicants' belief that the claims are in condition for allowance.

1. Anticipation Rejection - Claims 1-3, 5-9, 11, 12, 24, 37, 39 and 40

Claims 1-3, 5-9, 11, 12, 24, 37, 39 and 40 are rejected as anticipated based on either the Koyata reference, the Hake reference, or the Salerno reference. Each of these references is discussed in turn.

A. The Koyata Reference:

Applicants respectfully state that the Koyata reference does not disclose each and every element of claims 1-3, 6, 8, 11, 12, and 24. The Office Action states that the Koyata reference discloses "a rigid distal portion (5) connected to the main portion and having a distal end that is offset laterally from the main portion (5a) at an acute angle (Fig. 1) ...." Applicants submit this teaching cannot disclosed the claimed main portion and distal portion.

The Koyata reference states, in pertinent part: "tube 4 can be controllably bent by operating the string means by the operating knob 8 so that the distal end section 5 can be bent to such a position as indicated by reference numeral 5a." (col. 2, ll. 56-59). As such, element 5a, which is cited by the Office Action as the "main portion" is actually the distal end section 5 in a different position. In other words, Koyata reference numerals 5 and 5a are actually the same part, and as such, cannot disclose both the rigid distal portion and the main portion as claimed.

To the extent that the citation to Koyata reference numeral 5a was a clerical error, there are two other components in Koyata that may have been intended, which are hereby conditionally

addressed. Applicants reserve the opportunity to further address any rejection based on these components should the Examiner alter her position regarding which component of the Koyata reference forms the main portion.

Subject to this reservation, a controllably bendable tube 4 is disclosed. Applicants respectfully submit that Koyata's bendable tube 4 cannot fairly be considered a main portion as claimed. A flexible tube 3 is also disclosed in Koyata. This flexible tube 3, however, is not connected to the distal portion as claimed. As such, none of claims 1-3, 6, 8, 11, 12, and 24 are anticipated by the Koyata reference.

With regard to claim 3, the Koyata reference does not disclose a pre-curved rest orientation. As explained in the specification of the present application:

> The distal portion 16 is advantageously pre-bent or pre-curved through an acute angle α in the range of 3 to 30 degrees, most preferably 20 degrees, and is sufficiently stiff or flexurally rigid to substantially maintain the preselected acute angle. (p. 11, ll. 17-21).

The Koyata reference does not disclose this pre-curved rest orientation. Instead, it is explained that the distal end of the Koyata device is first directed to the desired location, and then tube 4 is bent. (col. 4, ll. 43-58). As such, claim 3 is not anticipated for this additional reason.

With regard to claim 6, it is specified that the distal portion includes a proximal end and a distal end, wherein the proximal end is axially aligned with the main portion, and the distal end diverges at an acute angle from the proximal end. There is no disclosure in the Koyata reference of a distal portion, which is stated by the Office Action as being distal end section 5, that includes a proximal end and a distal end diverging distally from the proximal end. As such, claim 6 is not

anticipated for this additional reason.

Claim 8 requires that the main portion and the distal portion are comprised of substantially the same material. This is explained in the specification that the material from which the main portion and the distal portion are made is substantially the same, but may have different flexibility resulting from differences in construction, such as wall thickness. (p. 9, l. 29 - p. 10, l. 5). There is no similar disclosure in Koyata. In particular, Koyata component 5 is disclosed as being preferably of a hard plastic. However, there is no discussion as to the composition of either bendable tube 4 or flexible tube 3. It appears that the "hard plastic" of component 5 would not be suitable for bendable tube 4 or flexible tube 3. Moreover, component 5a is merely distal end section 5 in a different position and cannot be both the main portion and the distal portion. As such, claim 8 is not anticipated by the Koyata patent for this additional reason.

Referring to claim 24, it is specified that the distal portion include a first end and a second end, and that the second end is angularly disposed relative to the first end. No such disclosure exists with the Koyata reference. Instead component 5 is disclosed only such that the first end and second end are co-linear, not angled relative to one another. Accordingly, claim 24 is not anticipated for this additional reason.

As discussed in the specification, a reason for the offset distal end is to prevent materials from being lodged in the distal end of the endoscope that would otherwise obscure the viewing field as it is guided down an endotracheal tube that may have biological materials collected therein. There is not disclosure to any similar purpose for the Koyata device.

For at least the reasons stated, applicants respectfully state that the Koyata patent does not

anticipate any of claims 1-3, 6, 8, 11, 12, and 24.

B. The Hake Reference:

Applicants respectfully state that the Hake reference does not anticipate any of claims 1-3, 6, 8, 11, 12, 24, and 37 because it does not disclose each and every claim element. The Office Action states, in relevant part, that "Hake shows an elongate viewing assembly for use as part of an endoscope, comprising: a flexible main portion (14b, 14c) ... and a distal portion (4a) [sic] connected to the main portion and having a distal end that is offset laterally from the main portion ... wherein the distal portion is substantially rigid...."

Applicants submit that segment 14A is identical to segments 14B and 14C and therefore, in actuality, is at best part of the main portion of the endoscope. Indeed, the Hake reference states that "[t]he flexible tube 10 is comprised of a series of connected segments 14. Each segment 14 ... constitutes a continuous portion of the tube 10 ...." (col. 4, ll .15-19). The Office Action has, in effect, taken the main portion of the endoscope and arbitrarily decided that it ends at a certain point and the remainder is a separate component. There is no grounds for doing so in that the Hake reference does not disclose that parts 14A can be considered a separate component.

Component 14A also does not form a distal portion having a distal end as claimed. As stated in Hake, "the construction and operation of the individual segments 14 is described by reference to the end segment 14A *near the distal end 12* of the endoscope." (col. 4, ll. 31-34). As such, the component 14A, which is suggested by the Office Action as the distal portion does not include a distal end.

As such, none of claims 1-3, 6, 8, 11, 12, 24 and 37 are anticipated. Various dependent claims are also not anticipated for further reasons discussed below.

With regard to claim 3, similar to the Koyata reference, there is no disclosure in the Hake reference to a pre-curved rest orientation. As such, claim 3 is not anticipated for this further reason.

With regard to claim 6, it is specified that the distal portion includes a proximal end and a distal end, wherein the proximal end is axially aligned with the main portion, and the distal end diverges at an acute angle from the proximal end. There is no disclosure in the Hake reference of a distal portion, wherein a proximal end has an *axis* that diverges distally from an *axis* of a distal end. The requirement of divergent axes denotes intersecting linear or substantially linear sections. The Hake reference, at best, discloses curved segments. As such, there is no axis for either a distal end or a proximal end of a distal portion. Thus, claim 6 is not anticipated for this additional reason.

Similarly, claim 12 also requires divergence of the distal portion relative to the main portion at an acute angle. Each of the segments 14 that make up tube 10 in the Hake reference are adjusted only in curved relation with one another. As such, there is no acute angle formed between any distal portion or main portion. Claim 12 is not anticipated for this additional reason.

Claim 24 similarly includes a requirement whereby a first end of the distal portion is angularly disposed from the second end of the distal portion. Each of the segments 14 that make up tube 10 in the Hake reference are adjusted only in curved relation with one another. As such, there is no angle formed between any first or second end of the distal portion. Claim 24 is not

anticipated for this additional reason.

The device disclosed in the Hake reference is also extremely complex compared to the claimed invention. The device disclosed in the Hake reference includes multiple moving parts controlled by inflatable and extendible conduits.

C. The Salerno Reference:

Applicants respectfully state that the Salerno reference also does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40 because it does not disclose each and every claim element.

Each of the claims of the present application specifies a flexible main portion. As explained in the specification, a flexible structure is such that the endoscope is capable of bending without excessive resistance as it is extended through a breathing tube. (p. 9, ll. 31-35). By contrast, malleable guides are those that can be bent or curved from its ordinarily straight configuration and hold the desired configuration without springing back to the original straight configuration. (p. 9, ll. 5-11).

As discussed in the specification, such malleable guides are generally not suitable for the purposes of the claimed invention. The probe disclosed in the Salerno reference is such a malleable guide – "[t]he instrument has a malleable stylet (or probe) ..." (col. 1, ll. 66-67). For this reason alone, the Salerno reference does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40.

Moreover, there does not appear to be any main portion or distal portion to disclosed in the Salerno reference. Applicants respectfully submit that the position that the curved sheath

shown in FIGURE 4 of Salerno discloses the claimed main portion and distal portion is untenable. As discussed, the Salerno probe 14 is malleable. Depending on where and to what degree the probe is bent, the main portion and distal portion would change from one procedure to the next.

The claims specifically require a main portion and a distal portion having a distal end. By contrast, the Salerno reference discloses a single probe having a distal end. There is no support for separating the continuous probe into different sections, such as a distal portion and main portion. Indeed, there is no difference in the structure of probe 14 from one end of the probe to the other. It should be noted that in the claims of the present application the distal end is a part of the distal portion. Salerno fails to disclose a distal portion. For this reason as well, the Salerno reference does not anticipate any of claims 1-3, 5, 8, 9, 11, 12, 37, 39, and 40.

2. Obviousness Rejection - Claims 4, 10, 13-17, 19-23, 25-36, 38, 41-42

Claims 4, 10, 13-17, 19-23, 25-36, 38, 41-42 are rejected as obvious in view of the Koyata reference, the Hake reference, or the Salerno reference, taken individually.

As discussed above, applicants respectfully submit that none of the Koyata reference, the Hake reference, or the Salerno reference disclose various features of the claimed invention. For this reason, the basic premise of the obviousness rejection – that the references teach all limitations of the claims except for the specific offset angle, offset distance and radius of curvature – is incorrect. As such, the obviousness rejection should be withdrawn.

Similarly, to the extent the cited prior art discloses an offset distal end, as is conceded in the Office Action, there is no suggestion in the prior art as to the particular claimed specific offset angle, offset distance and radius of curvature. A "[d]etermination of obviousness cannot be based

on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention." ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546 (Fed. Cir. 1998). A rejection based on obviousness requires a showing of a teaching, motivation, or suggestion to select and combine the references. See, e.g., McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351-52 (Fed. Cir. 2001). In other words, there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the applicant. In re Dance, 160 F.3d 1339, 1343 (Fed. Cir. 1998). This inquiry must be based on objective evidence of record. In re Lee, 277 F.3d 1338, 1343 (Fed. Cir. 2002); In re Dembiczak, 175 F.3d 994, 999 (Fed. Cir. 1999).

A stated objective of the claimed invention is to provide a device that can be guided through an endotracheal tube that may include a build-up of biological material without scraping the biological material, and thereby obscuring the endoscopic view. No similar objective is disclosed in any of the cited prior art. As such, there is no motivation to create the claimed specific offset angle, offset distance or radius of curvature.

At best, the statement that the cited prior art references can be bent at any angle, radius and distance indicates only a motivation to try to arrive at the specified offset, radius or distance. A motivation to try, however, is insufficient to establish a motivation or suggestion to adapt a prior art reference to arrive at the invention as claimed. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1380 (Fed. Cir. 1986).

With regard to the obviousness rejections of claims 41 and 42 in view of the Salerno patent, applicants respectfully disagree with the conclusion that placement of an endotracheal tube

over a stylet would render obvious inserting the same stylet within an already placed intubation tube. As discussed, the viewing of an already placed endotracheal tube involves several considerations such as the build-up of biological materials.

The two different procedures help illustrate some of the distinctions between the device disclosed in the Salerno reference from the claimed invention. The Salerno device is bent to accommodate a particular patient's anatomy so as to guide an endotracheal tube. In other words, the Salerno device must have sufficient rigidity to maintain its shape as the tube is slid over the probe. By contrast, the claimed viewing device is flexible so as to be guided down the endotracheal tube without disturbing the tube itself. The Salerno device, if used to inspect an already place endotracheal tube it would be too stiff to easily follow the path of the tube while being pushed from the outside. For these reasons, as well as those discussed previously, applicants respectfully submit that claims 41 and 42 are not obvious in view of the Salerno reference.

3. Objections to Drawings

Submitted herewith pursuant to §1.84 is replacement FIGURE 2. The correction to FIGURE 2 provides an indication for distal end 28 of the illumination optical fiber bundle 26.

With regard to the request to correct the drawings "because reference character '38' has been used to designate both proximal end and distal end," the specification has been amended above to indicate that the distal end is reference character "36" and the proximal end is reference character "38" as correctly indicated in FIGURE 2. As such, no correction to this portion of the drawing is necessary.

4. Conclusion

For the reasons stated above, applicants respectfully request withdrawal of the rejections and submit that the application is in condition for allowance and request same.

Respectfully submitted,

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